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Seth Lederman

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08/20/2010

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/992,235	<b>Applicant(s)</b> LEDERMAN ET AL.	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8,25-27,30,31,36 and 38 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8,30-31,36,38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

**Claims 1-8, 25-27, 30-31, 36 and 38 are presented for examination.**

Applicant's Amendment and Declaration of Dr. Harris under 37 C.F.R. 1.132 filed July 9, 2010 have each been received and entered into the present application.

Claims 1-8, 25-27, 30-31, 36 and 38 remain pending. Claims 25-27 remain withdrawn from consideration pursuant to 37 C.F.R. 1.142(b). Claims 1-8, 30-31, 36 and 38 remain under examination. Claims 37 and 39 are cancelled. Claims 1, 30, 36 and 38 are amended.

Applicant's arguments, filed July 9, 2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 30-31, 36 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth at p.3-7 of the previous Office Action dated January 12, 2010, of which said reasons are herein incorporated by reference.

Newly amended claims 1 and 30 now recite that the effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof is between 0.7 mg/kg-1.4 mg/kg.

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Newly amended claims 36 and 38 now recite that the effective amount of the claimed amphetaminil compound is between 0.8 mg/kg-1.3 mg/kg. Though it is noted that Applicant has amended the range of amounts circumscribed by the instant claims 1 and 30 to now read on the range of 0.7-1.4 mg/kg, which obviates the lack of written support issue *only* insofar as the previously claimed unit of mg/ml was not clearly described in the specification and claims as originally filed, the numerical range of 0.7-1.4 mg/kg remains unsupported by the original written disclosure for the same reasons described at p.3-7 of the previous Office Action dated January 12, 2010, which are herein incorporated by reference in their entirety, but will not be repeated herein for brevity of the record. In addition, the numerical range of amounts circumscribed by instant claims 36 and 38 has also been broadened from 0.8-1.2 mg/kg to now 0.8-1.3 mg/kg, which also remains unsupported by the original disclosure for the same reasons described at p.3-7 of the previous Office Action dated January 12, 2010, which are, again, incorporated by reference in their entirety, but are not repeated herein so as not to burden the record.

*Response to Applicant's Arguments and the Declaration of Herbert Harris under 37 CFR 1.132*

Applicant traverses the instant rejection, stating that the instantly claimed ranges are implicitly described in the instant application. Applicant relies upon the statistical analysis of Dr. Herbert Harris to show that the claimed ranges are implied in Figs.3A and 7A and that these data were used to generate the data in Figs.3C and 7C. Applicant alleges that determining the 95% confidence limits around the 1 mg/kg endpoint does not introduce new matter.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's traversal relies upon the declaration and statistical analysis of Dr. Herbert Harris as summarized in his declaration submitted under 37 C.F.R. 1.132. In the declaration, Dr. Harris states that he took the 95% confidence boundaries around the 1 mg/kg data point from Figs.3A and 7A and projected them onto a regression line that fit the data and then calculated the mg/kg values that correspond to the

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upper and lower 95% confidence bands. Dr. Harris states that it is his belief that the benefits of the claimed invention would be observed in the range of 0.8-1.3 mg/kg from the cumulative locomotor data (Fig.3C) and in the range of 0.7-1.4 mg/kg from the stereotypy data (Fig.7C). Applicant states that these ranges are based on data in the application as originally filed.

However, this statistical analysis purportedly underlying the now claimed dosage ranges is significantly flawed. Applicant relies upon the data in Figs.3A and 7A to derive 95% confidence intervals around the 1 mg/kg data point. However, Fig.3A reports the incidence of locomotor activity for the four experimental groups (i.e., vehicle, 0.1 mg/kg, 1 mg/kg and 10 mg/kg) over time following administration of (R,R'),(R,S')-amphetaminil sulfate. The error bars as presented in Fig.3A underlying the reported data points pertain specifically to the incidence of locomotor activity, *not*, as both Applicant and Dr. Harris appear to be alleging, with regard to variation above and below the specific dosage amounts administered to the treated rats. In fact, there is absolutely no variation, either explicit or implicit, of the dosage amounts administered. Only three specific amounts were provided to the tested rats, i.e., 0.1 mg/kg, 1 mg/kg and 10 mg/kg, not any amounts either above or below these particularly disclosed endpoints.

Thus, this alleged statistical analysis to determine 95% confidence intervals in and around the specified dosage amount of 1 mg/kg is clearly unsound because the calculation of a 95% confidence interval requires both a statistical sample (i.e., a series of measurements, of which there is apparently only one single data point of 1 mg/kg) and determination of additional statistical parameters, including a sample mean, standard error of the mean, etc. None of these parameters can be determined using a single data point of 1 mg/kg. As a result, the concept that there is any statistical analysis that can be performed to determine a 95% CI around the endpoint of 1 mg/kg is not understood. The study underlying Fig. 3A clearly administers a single discrete numerical concentration (i.e., in the instant case, 1 mg/kg) to determine the incidence of a particular side effect at this single discrete concentration. The only variable here with any reported error is the determination of locomotor activity, not the actual concentration that

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was administered. In other words, the only value that changes over the reported sample is the incidence of locomotor activity over time, *not* the dosage amount administered. This is a fixed concentration without variation and, therefore, the idea that one could then determine a range of mg/kg amounts from the reported data of a sample wherein the only variable measurement is locomotor activity seemingly flies in the face of standard statistical analysis. The same rationale applies to the information provided in instant Fig.7A, but for the fact that the reported data pertains to the incidence of stereotypy, and not locomotor activity as reported in Fig.3A.

What is additionally significant is the fact that Dr. Harris fails point to where in the original disclosure there is any description of the sample mean, standard deviation of error, 95% confidence intervals, etc. of *any* of the reported data points such that the data necessarily implied a range of amounts in the specification as originally filed. Dr. Harris allegedly based his calculations on the reported data points in conjunction with the reported error calculations, but the specification and claims as originally filed provide no description of the range of the reported data points such that this variation could be calculated solely from the original disclosure. Most importantly, the reported data points and error calculations pertain to a variable unrelated to the dosage amount (i.e., locomotor activity and/or stereotypy data) and, therefore, cannot be relied upon to determine a range of dosage amounts when the study used fixed concentrations of the claimed compound. In addition, Dr. Harris provides absolutely no description of his 95% confidence interval and/or regression line analysis that was employed to allegedly determine the now claimed dosage ranges of instant claims 1, 30, 36 and 38. As a result, both Applicant and Dr. Harris are relying upon extensive calculations that are unsupported by any factual evidence and, therefore, amount to no more than allegations without factual support, which are properly found unpersuasive. Arguments do not replace evidence where evidence is necessary, which is clearly apparent in the instant case, since the determination of clear written support hinges upon these alleged calculations by Dr. Harris, which are based upon data that is not clearly described in the specification as originally

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filed. See MPEP §2145. Accordingly, since the now claimed ranges are based upon ranges, 95% confidence intervals and error data that do not appear in the disclosure as filed, the claimed dosage ranges clearly constitute new matter and are properly rejected under 35 U.S.C. 112, first paragraph.

For these reasons *supra*, and those previously made of record at p.3-7 of the Office Action dated January 12, 2010, rejection of claims 1-8, 30-31, 36 and 38 is proper.

***Claim Rejections - 35 USC § 112, Second Paragraph (New Grounds of Rejection)***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Present claim 1 is directed to a pharmaceutical composition comprising a therapeutically effective amount between 0.7 mg/kg and 1.4 mg/kg of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically acceptable salt thereof, substantially free of (S,R'),(S,S')-amphetaminil, and at least one pharmaceutically acceptable diluent.

In particular, the phrase “effective amount” renders the metes and bounds of the instant claim indefinite because it is unclear for what the amount is therapeutically effective. Furthermore, Applicant has extensively discussed the effects of different amounts of (R,R'),(R,S')-amphetaminil on locomotor activity and stereotypy, which clearly supports the idea that the claimed “therapeutically effective amount” has different effects and, thus, the particular intended function of the therapeutically effective amount has not been explicitly set forth in the claims and renders the claims indefinite. This is because the claims themselves support the determination that many different effects of the compound are implied and, therefore, the intended effect of the amount instantly claimed is not clearly set forth because it is

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unclear as to for what, exactly, the amount must be therapeutically effective. See MPEP §2173.05(c)(III), which stated, “The phrase “an effective amount” has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Frederickson* 213 F.2d 547, 102 USPQ 35 (CCPA 1954).” Clarification is required.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 30-31, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salvesen et al. (“NMR and ORD Determination of the Configuration of the N-Cyanobenzylamphetamine (AN1)”, *Aezneim-Forsch. (Drug Res.)*, 1974; 24(2):137-140), in light of STN Registry File No.17590-01-1 (“Amphetaminil”, 2008) and Stedman’s Medical Dictionary (Twenty-Second Edition, 1972; p.377),



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each cited to show facts, in view of Remington's Pharmaceutical Sciences (Sixteenth Edition, 1980; p.420-425), each already of record, for the reasons of record set forth at p.7-10 of the previous Office Action dated January 12, 2010, of which said reasons are herein incorporated by reference.

Newly amended claims 1, 30, 36 and 38 are properly included in the instant rejection because the determination of the optimal dosage amount would have been a matter well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not been limited to, the age, body weight, symptoms, desired therapeutic effect, route of administration, duration of treatment, etc. Other factors that would have been considered would have included the sex, diet and medical condition of the patient, severity of the disease, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics, and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination, among others. Thus, the dosage amount of the instantly claimed compound that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed, absent factual evidence to the contrary.

*Response to Applicant's Arguments and the Declaration of Herbert Harris under 37 CFR 1.132*

Applicant traverses the instant rejection, stating that the amendments to the dosages reflect the 95% confidence limits around the 1 mg/kg data point and are dosages where the unexpected results of the claimed invention would be expected to be observed. Applicant relies upon the declaration of Herbert Harris to show that these dosage ranges would show more activity and fewer side effects versus other dosages.

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Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Applicant's attention is directed to Example 4 at p.31, which states: "(R,R'),(R,S')-amphetamine (Figure 3) increased locomotor activity only at the highest dose of 10 mg/kg (Fig.3A-B; significant effect of treatment ( $p < 0.001$ ), two-way ANOVA)." A comparison of the cumulative locomotor activity observed over 300 min for both (R,R'),(R,S')-amphetamine (Figure 3B) and for racemic amphetamine (Figure 4B) shows that, for both (R,R'),(R,S')-amphetamine and racemic amphetamine, a clear increase in locomotor activity was observed when 10 mg/kg s.c. was administered. Notably, also, a comparison of 0.1 mg/kg s.c. (R,R'),(R,S')-amphetamine and 0.1 mg/kg s.c. racemic amphetamine as presented in Figures 3B and 4B demonstrates that 0.1 mg/kg s.c. (R,R'),(R,S')-amphetamine showed greater locomotor activity than that seen with the racemate. Accordingly, the allegedly unexpected effect of decreased locomotor activity of the instantly claimed (R,R'),(R,S')-amphetamine sulfate isomer appears to only have been demonstrated at the 1 mg/kg s.c. amount when compared to the locomotor activity observed with equivalent amounts of the racemate.

Applicant's attention is further directed to Example 4 at p.32, which states: "(R,R'),(R,S')-amphetamine (Figure 7) tended to increase stereotypy at 10 mg/kg (Fig.7A-C) although differences did not reach statistical significance ( $p > 0.05$ , Kruskal-Wallis)." A comparison of the total stereotypy score observed over 300 min for both (R,R'),(R,S')-amphetamine (Figure 7B) and for racemic amphetamine (Figure 8B) shows that, for both (R,R'),(R,S')-amphetamine and racemic amphetamine, a clear increase in total stereotypy score was observed when 10 mg/kg s.c. was administered. Notably, also, a comparison of 0.1 mg/kg s.c. (R,R'),(R,S')-amphetamine and 0.1 mg/kg s.c. racemic amphetamine as presented in Figures 7B and 8B demonstrates an apparently equivalent total stereotypy score for both the single isomer instantly claimed and that of the racemate. Accordingly, the allegedly unexpected effect of decreased stereotypy of the instantly claimed (R,R'),(R,S')-amphetamine sulfate isomer appears to only have been

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demonstrated at the 1 mg/kg s.c. amount when compared to the total stereotypy observed with equivalent amounts of the racemate.

Thus, while it may be true that an unexpected effect has been demonstrated *solely* at the 1 mg/kg dosage amount of the instantly claimed (R,R'),(R,S')-amphetaminil sulfate with regard to reducing toxic effects in the form of locomotor activity and stereotypy, Applicant has failed to proffer any data supporting an unexpected effect beyond the 1 mg/kg data point, such as, e.g., across the now claimed range of 0.7-1.4 mg/kg (claims 1 and 30) or 0.8-1.3 mg/kg (claims 36 and 38). Note that the Examples of the instant specification fail to study any amounts between 0.1 and 1 mg/kg or between 1 mg/kg and 10 mg/kg such that one of skill in the art at the time of the invention would have been able to extrapolate the effect seen at 1 mg/kg to amount above and below 1 mg/kg. Most importantly, however, it is unclear at what critical point between 0.1-1 mg/kg or 1-10 mg/kg the amount become therapeutically inactive in providing the unexpected effect in reducing toxic effects in the form of locomotor activity and stereotypy.

Applicant attempts to overcome this deficiency by relying upon the Declaration of Herbert Harris under 37 C.F.R. 1.132, who alleges that it is his "belief that the statistical analysis of the 1 mg/kg dose points in Figures 3A and 7A show that similar unexpected results would be obtained in the ranges of 0.8-1.3 mg/kg or 0.7-1.4 mg/kg" (Declaration, p.3). However, this statement is unpersuasive because Applicant fails to proffer any data to support his allegation that the purportedly unexpected effect(s) would have been obtained over the range of dosage amounts now claimed. In addition, it is clear from the data as presented in Ex.4 and Figs.3-4 and 7-8 that there is a critical point between 0.1 mg/kg and 1 mg/kg and between 1 mg/kg and 10 mg/kg where the effect of the instantly claimed compound in reducing toxicity in the form of locomotor activity and stereotypy is not obtained. However, Applicant provides absolutely no study and/or data and/or explanation as to where this critical point lies between 0.1 mg/kg and 1 mg/kg or between 1 mg/kg and 10 mg/kg such that there would have been any basis to conclude that the allegedly unexpected effect would have occurred over the range(s) instantly claimed

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(i.e., between 0.7-1.4 mg/kg and 0.8-1.3 mg/kg). Thus, this allegation amounts to no more than the opinion and "belief" of Dr. Harris, which is unsupported by any evidence whatsoever, which is required by MPEP §716.01(c)[R-2] (which requires that any objective evidence should be supported by actual proof to be of probative value). Moreover, this submission of opinion evidence by Dr. Harris is directed to the ultimate legal question at issue (i.e., the range over which the unexpected effect would have been observed) and, therefore, is unpersuasive in view of the *factual evidence* already of record. As set forth by the MPEP at §716.01(c)[R-2](III), "Although an affidavit or declaration which states only conclusions may have some probative value, such an affidavit or declaration may have little weight when considered in light of all the evidence of record in the application. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973)."

In addition, both Applicant and Dr. Harris clearly admit, on the record, that the unexpected results of the claimed invention "would be expected to be observed" over the instantly claimed dosage ranges. The admission that a purportedly unexpected result *would have been expected to be observed* over the range of dosage amounts instantly claimed is clear evidence, provided by Applicant, that the effect is, in fact, not at all unexpected. An expectation of an allegedly "unexpected result" does not then make it unexpected, if one of skill in the art at the time of the invention would have expected it to occur. Thus, Applicant appears to have admitted on the record that the unexpected results are actually not unexpected, but rather would have been expected by the skilled artisan and, as a result, fail to amount to an "unexpected result" that would be a secondary consideration probative of nonobviousness.

Applicant is once again reminded that should he rely upon unexpected results to patentably distinguish over the prior art, the present claims must be limited to the embodiment(s) which is (are), in fact, unexpected. Note also that Applicant is burdened with the responsibility of explaining why the evidence provided to support secondary considerations is probative of non-obviousness beyond what data is explicitly provided as unexpected. Please see MPEP §716.02(b)[R-2], particularly Section (II), which

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states, “[A]ppellants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness.” *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992). In the instant case, though the instant data upon which Applicant relies was provided in the instant specification, the burden is nonetheless on Applicant to explain the data provided as evidence of non-obviousness of the claimed subject matter.

Moreover, Applicant is reminded that, “The submission of objective evidence of patentability does not mandate a conclusion of patentability in and of itself. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987).” In view of this, and further in view of the fact that the provided evidence fails to be commensurate in scope with the claimed subject matter for the reasons *supra*, the totality of the evidence of nonobviousness fails to outweigh the evidence of obviousness as set forth *supra* when all of the evidence is considered. Accordingly, the rejection is properly maintained.

For these reasons *supra*, and those previously made of record at p.7-10 of the Office Action dated January 12, 2010, rejection of claims 1-8, 30-31, 36 and 38 is proper.

### ***Conclusion***

Rejection of claims 1-8, 30-31, 36 and 38 is proper.

Claims 25-27 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Primary Examiner, Art Unit 1614

August 18, 2010